

JUN 14 2012

K111048

510(k) Summary

510(k) Summary	
Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Heather Guerin Senior Regulatory Affairs Specialist Telephone: 610-719-5432 Email: guerin.heather@synthes.com Facsimile: 610-719-5102
Date Prepared:	January 3, 2012
Trade Name:	Synthes Scout Tack Fixation
Classification:	21 CFR § 870.3470 Class II Cardiovascular Devices Panel Product Code: OMR (vessel guard or cover) 21 CFR § 888.3040 Class II Orthopaedic Devices Panel Product Code: NDM (pin, fixation, threaded, metallic)
Predicate Devices:	Synthes Scout Vessel Guard, K103558 Synthes Arch Fixation System, K032534 Replication Medical EnGuard Vessel Guard, K082782 Covidien Autosuture Tacker System, K090470
Device Description:	The Synthes Scout Tack Fixation is a method of fixation of the Scout Vessel Guard to bone. The single-use Scout Tack implant is made of a titanium alloy (TAN, per ASTM F1295-05, " <i>Standard Specification for Wrought Titanium-6Aluminum-7Niobium Alloy for Surgical Implant Applications (UNS R56700)</i> ," January 1, 2005). It has a low profile head. The tack is inserted by light impaction through the Scout Vessel Guard into lumbar vertebral bone. The Scout Tack implant can be used as an alternative to, or a complement to, suturing the Scout Vessel Guard in place.
Intended Use/Indications for Use:	The Scout Vessel Guard System is indicated as a cover for vessels during anterior vertebral surgery.
Comparison of the device to predicate device(s):	<ul style="list-style-type: none"> The Tack Fixation for the Synthes Scout Vessel Guard is substantially equivalent to suture fixation of the Scout Vessel Guard (as cleared in K103358) as demonstrated by pullout testing and dynamic mechanical and biomechanical testing and by usability testing in cadaver labs. The Tack Fixation for the Synthes Scout Vessel Guard is substantially equivalent to Synthes Arch Fixation System (K032534) in terms of material of manufacture (TAN), biocompatibility, intended use (fixation in the spine) and as demonstrated by pullout testing. The Tack Fixation for the Synthes Scout Vessel Guard is substantially equivalent to Replication Medical EnGuard Vessel Guard (K082782), as this device is marketed for fixation by means including tacks or staples. Hence the intended use of the device is the same as Scout Tack fixation of the Scout Vessel Guard. The Tack Fixation for the Synthes Scout Vessel Guard is substantially equivalent to the Covidien Autosuture Tacker System (K090470) in

510(k) Summary	
	material of manufacture, design (e.g. low profile, and helical geometry for bone purchase), pullout testing, and in intended use (fixation of prosthetic material during surgical procedures).
Performance Data (Non-Clinical and/or Clinical):	Synthes conducted the following non-clinical tests to support a determination of substantial equivalence: pullout testing, dynamic mechanical testing, dynamic biomechanical testing, and usability (cadaver lab) testing. Clinical testing was not required.
Conclusions:	The results of the non-clinical tests listed above support a determination of substantial equivalence because the Synthes Tack fixation performed equivalently to or superior to the predicate devices in these tests.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

JUN 14 2012

Synthes Spine
c/o Heather Guerin
Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, PA 19380

Re: K111048
Trade/Device Name: Synthes Scout Vessel Guard System
Regulation Number: 870.3470
Regulation Name: Intracardiac patch or pledget
Regulatory Class: II
Product Code: OMR, NDM
Dated: January 04, 2012
Received: January 05, 2012

Dear Ms. Guerin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device for reducing the incidence, severity, and extent of post-operative adhesion formation have not been established.

Furthermore, the indication for use as a cover for vessels during anterior vertebral surgery must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

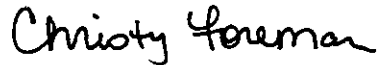
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Christy Foreman". The script is cursive and fluid.

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure

5 Indications for Use Statement

510(k) Number: K 111048
(if known)

Device Name: Synthes Scout Tack Fixation

Indications for Use:

The Scout Vessel Guard System is indicated as a cover for vessels during anterior vertebral surgery.

Prescription Use ☒
(21 CFR 801 Subpart D)

AND /
OR

Over-the-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. J. Killebrew

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111048